



California Legislature

Senate Committee on Business, Professions & Economic Development

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August 25, 2008

Mr. Gregory Schmidt
Secretary of the Senate
State Capitol, Room 400
Sacramento, CA 95814

Dear Mr. Schmidt:

I submit this letter to the Senate Journal to clarify legislative intent for Senate Bill 1307, regarding California's electronic pedigree (ePedigree) requirement for prescription drugs. The provisions of this bill reflect an agreement between myself, the California Board of Pharmacy (Sponsor) and members of the pharmaceutical distribution chain regarding California's efforts to protect consumers from counterfeit, diverted or misbranded drugs.

In response to threats to the prescription drug supply chain, California adopted an ePedigree requirement that was scheduled to go into effect January 1, 2007, to provide a system of tracking prescription drugs from the point of manufacture until they reach a pharmacy or hospital. However, the compliance date was delayed twice to 2009 and 2011 because of a number of technological and production line complexities. Many drug supply chain participants have expressed great concern in their ability to be ePedigree compliant by January 1, 2011. To give the pharmaceutical industry the necessary time, flexibility and guidance to comply with California law, I introduced SB 1307 to address a number of ePedigree implementation issues that were not addressed in the original legislation, including provisions that delay, for the final time based on this agreement, the effective date of the electronic pedigree requirement.

Over the course of the last 18 months, my staff attended and convened a number of stakeholder meetings to identify and develop statutory solutions to a number of unresolved ePedigree issues. Much of SB 1307 addresses implementation issues. At the request of the State and Consumer Services Agency, representatives of the pharmaceutical industry convened their own meetings for the purpose of attaining industry-wide consensus on the safest and most cost efficient way to protect California's drug supply. Representatives from drug manufacturers (brand and generic), wholesalers, retailers, independent pharmacies, clinics, hospitals, California counties and their respective trade organizations participated in those meetings and unanimously agreed to support SB 1307 if it was amended to (1) include specific language on preemption by subsequently enacted federal pedigree laws or regulations and (2) create



a graduated implementation schedule for compliance with the ePedigree law beginning on January 1, 2015, and ending on July 1, 2017.

In consultation with the Board of Pharmacy, I agreed to accept the amendments with the pharmaceutical industry's assurances that all involved parties will operate in good faith and in a diligent manner to implement the requirements as soon as possible and be fully compliant with the requirement by the dates contained in the bill. Those amendments were incorporated into SB 1307 on August 14th and the following organizations have now written in support of this measure:

California Board of Pharmacy (Sponsor)
Abbott Laboratories
Amgen
Arena Pharmaceuticals
Barr Pharmaceuticals
Baxter Healthcare
Bayer Healthcare
Biocom
California Healthcare Institute
California Pharmacists Association
California Retailers Association
California Society of Health-System
Pharmacists
California State Association of Counties
Cardinal Health
Compressed Gas Association
Council on Radionuclides and
Radiopharmaceuticals
Daiichi-Sankyo
Genentech
Generic Pharmaceutical Assn

Gray Panthers
Healthcare Distribution Management Assn
Hospira
Johnson and Johnson
McKesson Corporation
Merck, Inc.
Mylan, Inc.
National Association of Chain Drug Stores
National Coalition of Pharmaceutical
Distributors
Novartis Pharmaceuticals
Pfizer
Pharmaceutical Research and
Manufacturers of America (PhRMA)
Rite Aid
Sandoz, Inc.
Teva Pharmaceuticals, USA
Walgreens
Wyeth

After many months of negotiation and compromise, and with agreement on the part of all of the aforementioned organizations, SB 1307 now has the support and commitment of the entire pharmaceutical drug manufacturing and distribution chain to begin compliance with the ePedigree law beginning on January 1, 2015, and to be fully compliant by July 1, 2017. The delayed implementation dates in the August 14, 2008 amendments give the industry ample time to meet the state's electronic pedigree requirement. Therefore, SB 1307 represents the last time legislation will be needed to give the pharmaceutical industry time to comply with the state's electronic pedigree law and to ensure Californians have access to safe, lifesaving medication.

Sincerely,



MARK RIDLEY-THOMAS
Senator, 26th District